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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,203	10/27/1999	CHRISTOPHER O. OKUNJI	003/172/SAP	4366
7590 ELIZABETH A. ARWINE USAMRMC FORT DETRICK BUILDING 521 FREDERICK, MD 21701				
06/04/2010				
EXAMINER				
FLOOD, MICHELE C				
ART UNIT		PAPER NUMBER		
1655				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/428,203

Applicant(s)

OKUNJI ET AL.

Examiner

MICHELE FLOOD

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 30 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 30 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/02)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on March 16, 2010.

The objection set forth in the previous Office action mail dated November 16, 2009 has been overcome by Applicant's amendment to Claim 30.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 11, 30 and 38 are under examination.

Response to Arguments

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. 102(b), a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue*, 766 F.2d 531, 533, 266 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose each limitation of the claimed invention, *MEHL/Biophile Int'l Corp. v. Milgram*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art, the prior art must necessarily

function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the functions of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejections - 35 USC § 102

Claims 1, 11, 30, as amended, and 38 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kapundu et al. (U; Translation of foreign language non-patent literature of Kapundu et al. *Phytochemistry* (1980); 19(4): 615-622. New triterpenoids from *Napoleonaea imperialis* provided herein.). The rejection remains for the reason set forth clearly in the previous Office action and repeated herein for convenience.

Applicant claims a biologically active extract comprising a fractionated extract from *Napoleonaea imperialis*, wherein said extract is obtained using an organic solvent; and wherein said biologically active is saponin-enriched and exhibits anti-leishmanial activity. Applicant further claims a biologically active extract according to claim 1, wherein said solvent is methanol, and wherein said extract is obtained directed from solvent extraction of powdered seeds of said plant utilizing said solvent. Applicant further claims a biologically active extract according to claim 11, wherein said solvent is methanol.

Applicant's main argument is directed to the idea that the Examiner has misapplied the inherency doctrine. Applicant further argues that the Examiner has not

responded to arguments set forth by Applicant in response to previous Office actions, with regard to the anticipatory teachings of Kapundu, et al. Applicant is mistaken. Applicant is invited to revisit the Non-Final Office action mail dated May 30, 2007 wherein the Examiner properly responded to each and every argument presented in Applicant's "REMARKS" filed on December 20, 2006, as well as its associated 1.132 declaration filed by Christopher O. Okunji, Ph. D.

Applicant further argues that the teachings of Kapundu '[are] is strictly dependent upon the hydrolyzed seed extracts of *N. imperialis*'. Applicant further argues limitations neither persuasive nor commensurate in scope to the limitations of the claimed invention, such as Applicant's pursuit of 'only naturally occurring pharmacologically active compounds . . . rather than hydrolyzed products . . . present knowledge on *N. imperialis* indicated that the major constituents of this plant are saponins . . . saponin contents have been reported to vary depending on factors (discussing geographic location) . . . saponin distribution among the organs of a plant may vary considerably (citing as example the variation in saponin concentration in marigold flowers varies significantly from that of the roots) . . . Our work on *Dracaena* species revealed that very high saponin content are found mostly in the seeds." See Applicant's §132 affidavit at 6. Note also that Applicants specifically discuss the problems associated with hydrolysis of saponins as taught by Kapundu, et al. These include complications with artifact formation, low yields, low selectivity and difficulty with structure elucidation. See id at 8.' Applicant's arguments have been fully considered. However, Applicant's repeatedly raised in rebuttal arguments during prosecution are not relevant to the expressed

teachings of the reference. For instance, the Examiner has carefully considered Applicant's position that the Kapundu' reference fails to teach the instantly claimed invention and Applicant's reasoning for the distinction between what is disclosed by Applicant and what is taught by the prior art reference. However, Applicant's arguments are not persuasive because Kapundu clearly teaches a methanol extract from powdered seeds of *Napoleonaea imperialis*, on page 615, Column 2, lines 11-12. Furthermore, Kapundu expressly teaches that the methanolic powdered seed extract of the claim-designated plant comprises saponin. For example, on page 615, last line bridging page 616, line 1, Kapundu clearly teaches extracting the seeds of *Napoleonaea imperialis* with methanol and adding water to the methanolic extract to precipitate a saponin, which is separated by filtration. While Kapundu does teach identification of compounds contained therein the methanolic seed extract, thus necessitating a hydrolysis step of the extract, such disclosure by Kapundu does not negate the fact that Kapundu expressly teaches a methanolic extract obtained from powdered seeds of the claim-designated plant containing a saponin fraction therein. Therefore, while Kapundu does not expressly teach that the prior art methanolic plant extract has biological activity *per se*, biological activity is inherent to the extract taught by Kapundu because the source of the plant, the particular plant material from the source plant, and the solvent used in the making of the plant extract taught by Kapundu are one and the same as instantly claimed by Applicant. Therefore, antileishmanial activity extract of the methanolic extract of powdered seeds of *Napoleonaea imperialis* taught by Kapundu is inherent to the referenced extract, absent evidence to the contrary.

The reference anticipates the claimed subject matter.

No claims are allowed.

Applicant's summary of the most relevant portions of the prosecution history of the instant application and associated rebuttal arguments, with regard to Kapundu, is noted. Applicant asserts:

"In subsequent communications with the Examiner, namely a telephonic interview, Applicants' proposed amendments likely would have placed the application in condition for allowance. The Examiner noted that the only condition against allowance would be the discovery of prior art that reads on the claimed invention. See Interview Summary Record of

July 24, 2008. However, the Examiner issued an Advisory Action on August 21, 2008, stating that the amendment was not entered because "Applicant's insertion of the limitation 'fractionated' would require further search and/or consideration¹²²". See Note 3 of the Advisory Action, August 21, 2008. Applicants filed an Appeal Brief on May 22, 2009, on several grounds, including the fact that the term "fractionated" was suggested by the Examiner in the Office Action of March 28, 2008, that initiated the telephonic interview, and the Applicants' reliance on the Examiner's explicit statements made in the Interview Summary Record. Kapundu, et al., is not mentioned in any of these communications.

Applicants respectfully traverse the Examiner's rejection and contend that the present Office Action is outside the scope of examination practices. While reopening of prosecution provides the Examiner a procedural mechanism to enter the claims, newly rejecting them on Kapundu, et al., is questionable as the amendments to the claims were addressed by the Examiner in the Telephonic Interview and the subsequent Advisory Action, neither of which mention the Kapundu, et al., reference. Furthermore, Applicants note that the Examiner presents the same inherency arguments (see rebuttal arguments below) that she had presented in her Office Actions prior to March 28, 2008, and ceased to continue thereafter. Such practices do not further prosecution and fail to provide Applicants the full and bona fide examination practices to which they are entitled.

Additionally, please note that the current Office Action makes no mention of the prior art rejection of the Office Action of March 28, 2008. Based on the prosecution history, it is the Applicants' strong position that the omission of the Kapundu, et al., reference in the March 28, 2008, Office Action, and the omission of the Okunji, et al., reference in the November 16, 2009, Office Action are explicit showings that both references have been overcome."

Applicant's arguments have been fully considered. However, with regard to the "Interview Summary" mail dated July 24, 2008, the record does not indicate the term "fractionated" was discussed, let alone any mention of the Examiner suggesting Applicant to amend the claims to recite "fractionated". While the Examiner did indeed

indicate 'Amending the claims as discussed would appear to obviate the rejections of record and place Claims 1, 11, 30 and 38 in condition for allowance absent discovery of prior art that reads on the claimed subject matter', the record shows that Applicant proposed limiting the species recited in Claim 1 to *Napoleonaea imperialis* and cancelling Claims 2-10, 12-29 and 31-35. Accordingly, the issuance of the Advisory Action mail dated August 21, 2008 was proper. Finally, in an Appeal Brief conference the Examiner along with Supervisory Patent Examiners Terry McKelvey and Jon Weber in attendance, upon review of the prior art made of record, it was determined that the 'Kapundu' reference read on the claimed invention. Thus, it was considered that expeditious prosecution of Applicant's claimed invention was best advanced by entering the amendment filed on July 24, 2009 in the Appeal brief.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE FLOOD whose telephone number is (571)272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
June 2, 2010

/Michele Flood/
Primary Examiner, Art Unit 1655